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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/535,182 03/27/00 RAGAB

M OC010170

HM12/0818

ARTHUR MANN
SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT, K-6-1, 1990
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EXAMINER

GOLDBERG, J

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 08/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/535,182

Applicant(s)

Ragab

Examiner
Jerome D. Goldberg

Group Art Unit
1614



☒ Responsive to communication(s) filed on Mar 27, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-19 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-19 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1614

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Dhodapkar et al reference taken with the Nicholson et al reference. The Dhodapkar et al reference ^{shows} applicant's compound temozolomide (TMZ) being "administered p.o. at doses ranging from 50 mg/m²/day to 250 mg/m²/day for 5 days, every 4 wk" (lines 8 and 9 of abstract). The Nicholson et al. reference teaches administering TMZ "orally for 5 days, with subsequent courses administered every 21 to 28 days... Dose levels tested included 100, 150, 180, 215, 245 and 260 mg/m² daily" (lines 5-7 of abstracts). The reference do not teach all the steps in the claims, including the rest period of 5-14 days. Accordingly, one skilled in this art would be motivated to modify the resting period and closing period in the absence of a side-by-side comparison.

Claims 12-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the CA 2,184,545 patent. The CA 2,184,545 teaches a capsule containing 5 mg of temozolomide (See Abstracts last three lines). The claim is directed to a kit containing a 5 mg unit dose form of temozolomide and a pharmaceutical acceptable carrier. Accordingly, one skilled in art would be motivated to use the prior art unit dosage form in a kit. With regard to the use limitations in the claim, said use limitations are of no value in a composition claim.

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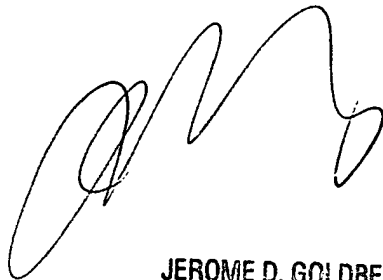
Any inquiring concerning this communication or earlier communications from the examiner should be directed to Examiner J.D. Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. to 3:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone numbers for this Group are (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Goldberg/sgl

8/11/00



**JEROME D. GOLDBERG
PRIMARY EXAMINER
GROUP 1200**